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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,514	04/30/2001	K. Roger Aoki	D2929CON	3428

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,514	AOKI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office Action is responsive to Applicant's response filed March 21, 2002. The previous Office action (paper No. 6) mailed December 21, 2002 is a non-final action. Page 2 of the previous action was titled Final Action. However, the Office Action Summary, shows that the action was a non-final action. The Office apologizes for the inconsistency.

2. The amendment submitted March 21, 2002 is acknowledged. Claims 1,8, 24 and 28 have been amended.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. In view of Applicant's amendment the following Objections and Rejections have been withdrawn:

a) Rejection of claims 17-29 under 35 U.S.C. 102(b), pages 2-3, paragraph 6 of the previous Office action.
b) Rejection of claims 1-9 under 35 U.S.C. 103(a), pages 4-5, paragraph 7 of the previous Office action.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(e) as anticipated by Arnon *(U.S. Patent No. 5,562,907, published October 8, 1996).*

Claims 1-4 and 6-9 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition comprising the step of administering simultaneously to a patient a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G an amount of each selected neurotoxin being selected to control a duration of therapeutic activity of the administered neurotoxins.

Arnon teaches a method of providing toxin therapy to a human patient who has a neuromuscular disorder comprising administering a therapeutically effective amount of

botulinum toxin (column 12, lines 4-7). Arnon teaches that various botulinum toxin combinations are used in the invention (column 14, lines 1-9). Characteristics such as duration of treatment for therapeutic activities would be inherent in the method of Arnon.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 17-20 and 22-28 are rejected under 35 U.S.C. 102(e) as anticipated by Arnon *(U.S. Patent No. 5,562,907, published October 8, 1996).*

Claims 17-20 and 22-28 are drawn to a composition suitable for treating a patient suffering from a neuromuscular disorder or condition said composition comprising a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum types A, B, C, D, E, F and G an amount of each selected neurotoxin being selected to control a duration of therapeutic activity of the neurotoxins.

Arnon teaches that various botulinum toxin combinations are used in the invention which include botulinum types A, B, C, D, E, F and G (column 14, lines 1-9). Limitations such as "treatment for joint dislocations, relaxation for physical therapy, alleviation of muscle spasm, immobilization of a joint undergoing surgery, for prevention of muscle contractions prior to or after surgery, treating tendon and ligament repair,

treatment of scoliosis and spasm of sphincter muscles" are being viewed as limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-9 and 17-29 are rejected under 35 U.S.C. 102(e) as being anticipated by or under 103(a) as being obvious over Borodic *(U.S. Patent No. 5,401,243, published March 28, 1995).*

Claims 1-9 and 17-29 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition comprising the step of administering simultaneously to a patient a therapeutically effective amount at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G an amount of each selected neurotoxin being selected to control a duration of therapeutic activity of the administered neurotoxins.

Borodic teaches a method of treating a patient with botulinum toxin preparations against unwanted involuntary pathologic muscle stimulations, i.e. spasm, rigidity or hyperstimulation, by direct injection throughout or in the area of innervation of the affected muscle or muscles (column 5, lines 38-42). Borodic teaches experimentally produced botulinum toxin formulations and subtypes (column 3, lines 6-9). Borodic teach that the drug (i.e. botulinum toxins) of the invention may be used to alleviate overstimulation, rigidity, spasticity in muscle or muscles groups caused by stroke, cerebral palsey, multiple sclerosis, unilateral or bilateral parkinsonism and other diseases characterized by spasmodic or continuous muscle hyperstimulation (column 5, lines 42-50).

Borodic does not teach specific botulinum toxin combinations (i.e. A and B, A and C, and so forth). However, in the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include any botulinum toxin subtype or combinations thereof in the method of Borodic because Borodic et al teach that botulinum toxin-derived pharmaceuticals may take on any form of botulinum toxins A through G or various engineered proteins which retain the native form's ability to block acetylcholine release (column 5, lines 7-12). It would have been expected, barring evidence to the contrary, that any botulinum toxin subtype or a combination thereof would be effective in treating unwanted involuntary pathologic muscle stimulations.

Status of Claims

8. No claims are allowed.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 12, 2002

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